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| 10/524,860 | 02/18/2005 | Takeshi Koizumi | Q86151 | 2817 |
| 23373 7590 11/28/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 | | | EXAMINER WOOLWINE, SAMUEL C | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,860

Applicant(s)

KOIZUMI ET AL.

Examiner

SAMUEL WOOLWINE

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38, 49 and 50 is/are pending in the application.
- 4a) Of the above claim(s) 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status

Applicant's response filed 08/14/2008 is acknowledged. Claims 38, 49 and 50 remain in the application. Claim 49 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/09/2007 [because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a))].

Any previous rejections of a claim which has been cancelled are withdrawn as moot.

The rejections of claims 38 and 50 under 35 U.S.C. 112, 2nd paragraph, made in the Office action mailed 05/14/2008, are withdrawn in view of Applicant's amendments.

The rejection of claim 38 under 35 U.S.C. 103(a) over Warner in view of Torriani, Stine, and GenBank Accession Numbers AF311535, AF311574-311576, AF311578-311583, AF311585-311586, and AF311589-311596 is withdrawn in view of Applicant's amendment, since the amendment requires a primer comprising the entire sequence of SEQ ID NO:17 (ignoring the non-elected SEQ ID NOs) is maintained for the reasons of record and reiterated below.

The rejection of claim 50 under 35 U.S.C. 103(a) over the above references and further in view of the Stratagene catalog is maintained for the reasons of record and reiterated below.

New rejections are set forth below, necessitated by Applicant's amendment. Previously, claim 38 required that the gene amplification primer was not more than 40 nucleotides in length, and therefore previous claim 44, which depended from claim 38 and further required the primer to contain SEQ ID NO:17, and therefore also required the primer to be not more than 40 nucleotides in length. Amended claim 38 now only requires the primer to comprise the sequence of SEQ ID NO:17, and no longer has any upper limit on length. This has prompted the new grounds of rejection.

Applicant's remarks will be addressed following the rejections.

Claim Objections

Claims 38 and 50 are objected to because claim 38 has been amended to encompass non-elected species. The Office action mailed 03/07/2007 required an election of species of either a particular combination of nucleotide positions or a single particular sequence (page 4). In the response filed 04/09/2007, Applicant elected the primer of claim 44 (i.e. SEQ ID NO:17). Applicant is required to cancel the non-elected SEQ ID NOs from claim 38; there is no longer a generic claim. The rejections below apply to the elected species (SEQ ID NO:17).

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

With regard to claim 38, GenBank GI:16565115 discloses a nucleotide sequence comprising the sequence of SEQ ID NO:17 (note: Qy is the sequence of SEQ ID NO:17, where "R" is the IUPAC nucleotide symbol representing either A or G, and Db is a portion of the sequence of GenBank GI:16565115):

Qy 1 CCTGTGTATGCGAAGAARCTT 21
|||||||:|
Db 238 CCTGTGTATGCGAAGAAGCTT 258

Claim Rejections - 35 USC § 103

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank GI:16565115 (prior art of record) in view of the 1988 Stratagene Catalog.

The teachings of GenBank GI:16565115 have been discussed. The GenBank record does not teach putting this primer into a kit.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to put the primer disclosed by the GenBank record into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches advantages of kits: "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms,

desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control." (page 39, column 1).

Previous Rejections

Claim Rejections - 35 USC § 103

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Warner et al (Applied and Environmental Microbiology 65(3):1141-1144; 1999) in view of Torriani et al (Applied and Environmental Microbiology 67(8):3450-3454; 2001), Stine et al (Infection and Immunity 68(12):7180-7185; 2000; cited on the IDS of 02/18/2005) and GenBank Accession Numbers AF311535, AF311574-311576, AF311578-311583, AF311585-311586, and AF311589-311596 (cited on the IDS of 07/11/2006, each of which was publicly available on 1 November 2001).

Warner teaches a method for discriminating *Vibrio* species from one another, as well as differentiating between *V. vulnificus* strains using randomly amplified polymorphic DNA analysis (see entire article).

Warner does not teach primers corresponding to the claimed primers, which Applicant made based on differences in the sequence of the *recA* gene between *V. vulnificus* and other *Vibrio* species.

It was known in the prior art to design species-specific primers, based on differences in the sequence of the *recA* gene among related bacterial species, in order to differentiate among the related species. Torriani teaches this with respect to discriminating among species of the genus *Lactobacillus*. Of randomly amplified polymorphic DNA-PCR (the method used by Warner), Torriani states: "such methods are not suitable for routine identification requirements" (page 3450, column 1, second paragraph). As an improvement over such methods, Torriani teaches: "PCR using species-specific oligonucleotides designed based on phylogenetic molecular markers could be a useful approach...It has been proposed that the *recA* gene could be used as a phylogenetic marker, and it has already given satisfying results for many bacterial genera..." (page 3450, column 2, first full paragraph, citations omitted). Torriani then goes on to design such primers for *Lactobacillus* (see entire article).

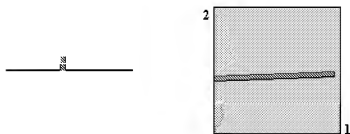
Stine sequenced *recA* from 113 *Vibrio cholerae* strains and closely related species, including *Vibrio vulnificus* (see abstract and Table 1). Stein states: "The locus chosen for study was *recA* because it has been shown to be useful for estimating phylogeny, in contrast to some other genes" (page 7180, column 1, second paragraph, citations omitted). Stine also remarks: "As expected, the *Vibrio vulnificus* and *Vibrio parahaemolyticus* sequences formed out-groups" (page 7821, column 1, first full paragraph). Hence, Stine provided a reasonable expectation of success in using *recA* sequence differences to discriminate *Vibrio vulnificus* from other *Vibrio* species.

The GenBank Accession Numbers represent a collection of *recA* sequences from 20 strains of *Vibrio vulnificus* submitted to the GenBank database by Benagli and

colleagues on 6 October 2000, and which were made publicly available at least as of 1 November 2001. To confirm that this collection of known *V. vulnificus* *recA* sequences would have provided the information necessary to arrive at a *V. vulnificus*-specific primer as set forth in the claims, the sequence of SEQ ID NO:17 (Applicant's elected SEQ ID NO, as recited in claim 38) was compared to one of the GenBank sequences (AF311535, which is GenBank GI:16565115):

Sequence 1: SEQ ID NO:17
Length = 21 (1.. 21)

Sequence 2: gi16565115[Vibrio vulnificus strain 9067-96 recombinase A (recA) gene, partial cds]
Length = 543 (1.. 543)



NOTE Bitscore and expect value are calculated based on the size of the nr database.

NOTE If protein translation is reversed, please repeat the search with reverse strand of the query sequence.



Score = 39.9 bits (20), Expect = 0.045
Identities = 20/21 (95%), Gaps = 0/21 (0%)
Strand=Plus/Plus

```
Query 1 CCTGTGTATGCGAAGAARCTT 21
      |||
Sbjct 238 CCTGTGTATGCGAAGAAGCTT 258
```

It is noted that R is the IUPAC symbol used to designate either A or G.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method used by Warner by following the

example of Torriani, who described an improved method of discriminating among bacterial species using species-specific primers based differences in the *recA* gene among those species. Therefore, one of ordinary skill would have been motivated to use the known *Vibrio vulnificus recA* sequences available in GenBank to design species-specific primers for the purpose of discriminating *Vibrio vulnificus* from other *Vibrio* species. Both the disclosures of Torriani and Stine explicitly suggest *recA* as a marker for discrimination among species of related bacteria.

In *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the Supreme Court stated: "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill" (at 1389). The same rationale would apply to improving upon one prior art method based on a similar improvement to another prior art method (see MPEP 2143(C)). Torriani clearly recognized that species-specific differences in *recA* had allowed discrimination among other related bacteria, and so applied this knowledge to *Lactobacillus*. Likewise, the ordinary practitioner would have been motivated to apply the knowledge from Torriani's disclosure to the design of similar primers for *V. vulnificus*.

In following this course, one would have inevitably identified which nucleotides in *recA* were specific for *V. vulnificus* (as well as which were specific for other *Vibrio* species). As these differences were not numerous, one would have been guided by those "specific" bases when choosing appropriate species-specific primers for *V.*

vulnificus. As the Court noted in *KSR*, "[g]ranteeing patent protection to advances that would occur in the ordinary course without real innovation retards progress" (at 1389). Such is the case here, for Applicant has arrived at the claimed primers simply by applying what others have done before with other microorganisms to *Vibrio vulnificus*. While the work involved may have been significant, it does not represent "real innovation".

Furthermore, one would have been motivated to incorporate as many "specific" bases into the primers as possible, in order to maximize the specificity of the primer. Hence, one would have been motivated to incorporate "at least two" and possibly more depending on how closely spaced the "specific" bases were to one another.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Warner et al (Applied and Environmental Microbiology 65(3):1141-1144; 1999) in view of Torriani et al (Applied and Environmental Microbiology 67(8):3450-3454; 2001), Stine et al (Infection and Immunity 68(12):7180-7185; 2000) and GenBank Accession Numbers AF311535-AF311596 as applied to claims 38 above, and further in view of the 1988 Stratagene Catalog.

The teachings of Warner, Torriani, Stine, and GenBank have been discussed. These references would not necessarily have directed one to incorporate the *Vibrio vulnificus*-specific *recA* primers suggested by the combined prior art of Warner, Torriani, Stine and GenBank into a kit.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to incorporate the *Vibrio vulnificus*-specific *recA* primers suggested by the combined prior art of Warner, Torriani, Stine and GenBank into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches advantages of kits: "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control." (page 39, column 1)

Response to Arguments

Applicant's arguments filed 08/14/2008 have been fully considered but they are not persuasive.

Applicant's first argument (beginning middle of page 7 of the response) is that whereas the rejection set forth a reason to modify a prior art *method*, the instant claims

"do not claim a generic method for distinguishing *Vibrio vulnificus* from other *Vibrio* species" but instead are "directed to *specific* primer sequences that exhibit superior specificity in such a method". This argument is not persuasive because the rejection sets forth the rationale to arrive at the claimed primers, and whether this was the same reason for which Applicants made the claimed invention is irrelevant. In this case however, it appears the rationale is the same, and Applicant is arguing that the claimed primers are of "superior specificity". Whether Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Furthermore, Applicant's allegations of superior results are not substantiated by any evidence, such as comparing the claimed primers to other primers derived from the known sequences of the *Vibrio recA* gene. It is clear that one could arrive at more than one primer based on *recA* to distinguish among *Vibrio* species (in fact, Applicant's disclosure teaches several). However, allegations of unexpected results must be factually supported (see MPEP 716.01(b)(I)).

Applicant's next argument is to cite Torriani (a reference relied on in the rejection) as teaching that prior art attempts to design species-specific primers to distinguish among *Lactobacillus* species lacked sufficient specificity. The passage cited in Torriani mentions a paper (cited as reference 3 in the Torriani article) where the primers used did not guarantee sufficient specificity. Looking at the title of the reference (see page 3453, cited reference 3 of Torriani), it is clear that the primers in question were targeting

the 16S/23S rRNA [ribosomal RNA] spacer region. In the paragraph following Torriani's mention of these unsuitable primers, Torriani explains "16S ribosomal DNA sequences are not suitable because of the high identity value (>99%) shared by *L. plantarum* and *L. pentosus*". Hence, Torriani proposed to use *recA* instead. Therefore, Torriani teaches the reason why primers may fail to distinguish among related species (i.e. because they are based on sequences that are not sufficiently different among the groups of organisms to be distinguished). Therefore, there was not a problem of unpredictability, as Applicant asserts, but rather the matter of choosing a target with enough differences among related organisms as to allow discrimination.

Furthermore, with regard to predictability, the legal standard for "reasonable expectation of success" is provided by case law and is summarized in MPEP 2144.08, which notes "obviousness does not require absolute predictability, only a reasonable expectation of success; i.e., a reasonable expectation of obtaining similar properties. See, e.g., *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988)." In this factual case, there is express suggestion in the prior art that *recA* was a suitable target for distinguishing *Lactobacillus* species as well as "many bacterial genera", as discussed by Torriani (page 3450, column 2, first full paragraph). Furthermore, Stine specifically distinguished among *Vibrio* species, including *V. vulnificus*, based on sequence differences in the *recA* gene. This sufficient for a reasonable expectation of success. The MPEP cites *In re O'Farrell*, which notes regarding "obvious to try" at page 1682 that,

"In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were

critical or no direction as to which of many possible choices is likely to be successful. e.g., *In re Geiger*, 815 F.2d at 688, 2 USPQ2d at 1278; *Novo Industri A/S v. Travenol Laboratories, Inc.*, 677 F.2d 1202, 1208, 215 USPQ 412, 417 (7th Cir. 1982); *In re Yates*, 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981); *In re Antonie*, 559 F.2d at 621, 195 USPQ at 8-9. In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *In re Dow Chemical Co.*, 837 F.2d, 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 1606 (1987); *In re Tomlinson*, 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966).

The court in O'Farrell then, affirming the rejection, notes "Neither of these situations applies here." For the instant case, it is clear that neither situation applies here either. This is not a situation where the prior art suggests varying a variety of parameters, since the prior art directly points to the use of *recA* sequence differences. This is also not a situation where only general guidance was given. The prior art provides specific guidance because the sequences of numerous *Vibrio recA* genes were known and available, as will be discussed further below.

Next, Applicant argues that one of skill in the art would not have arrived at the claimed primers based solely on the recited Genbank sequences, since these all pertain to *V. vulnificus recA* sequences, whereas the claimed primers were selected based on a comparison of *recA* sequences from "a wide array of *V. vulnificus* and non-*V. vulnificus Vibrio* strains". It is respectfully submitted that the rejection is not based "solely on the recited Genbank sequences" but also includes the disclosure of Stine. Stine sequenced the *recA* genes from 113 *Vibrio cholerae* strains and closely related species (see abstract). These related species (based on the phylogenetic analysis shown in figure 2) included *V. vulnificus*, *V. parahaemolyticus* and *V. mimicus*. Furthermore, Stine evidences that these sequences were publicly available: see page 7184, column 1, last

statement: "Individual sequences were entered into GenBank as accession no. AF301020 through AF301131."

Therefore, between all of the sequences disclosed in the GenBank sequences cited in the rejection and those which Stine evidences were known in the prior art, it is respectfully asserted that a sufficient amount of diversity in the *recA* sequences from *Vibrio* species was known in the art as to render the sequence of SEQ ID NO:17 obvious for use as a primer to distinguish *V. vulnificus* from other *Vibrio* species.

The arguments presented for claim 50 rely on the same reasoning as the arguments for claim 38, which have already been addressed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Woolwine/
Examiner, Art Unit 1637

/Young J Kim/
Primary Examiner, Art Unit 1637